UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BETTY DUPERE,	:	
Plaintiff,	:	
v.	:	**CASE No.:** 7:21-cv-02605
ETHICON, INC. and JOHNSON & JOHNSON,	:	**JURY TRIAL DEMANDED**
	:	**ASSESSMENT OF DAMAGES HEARING IS REQUIRED**
Defendants.	:	
	:	**JURY TRIAL DEMANDED**
	:	

COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff BETTY DUPERE files this Complaint and for causes of action against Defendants, ETHICON, INC., and JOHNSON & JOHNSON ("Ethicon Defendants") and alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than one or more of the Defendants.

2. At all times material hereto, Defendants were engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including New York, either directly or indirectly, medical devices intended to treat stress urinary incontinence and/or pelvic

organ prolapse, including the Ethicon Gynecare TVT ("Pelvic Mesh Product") that was implanted in Plaintiff in New York.

3. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff was implanted with the product at issue in this district and was injured in this district.

4. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Southern District of New York because Defendants placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a Florida resident, in the State of New York. Each Defendant has sufficient minimum contacts in New York or otherwise intentionally avails itself of the New York market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the New York courts consistent with traditional notions of fair play and substantial justice.

PARTIES

5. Plaintiff BETTY DUPERE is a citizen and resident of Florida who was implanted with Defendants' defective medical device at the Mount Sinai Medical Center in New York, New York.

6. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson with its corporate headquarters in Somerville, New Jersey. Defendant Ethicon is a foreign corporation licensed to do business in the State of New York and may be served with process by serving its registered agent, Office of the New York Department of State, One Commerce Plaza, 99 Washington Avenue, Albany, NY 12231. Defendant Ethicon, Inc. is a wholly

owned subsidiary of Defendant Johnson & Johnson.

7. Defendant Johnson & Johnson (sometimes referred to herein as "J&J") is a New Jersey corporation that has its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey. Defendant Johnson & Johnson does business in the State of New York and may be served with process by serving its registered agent, Office of the New York Department of State, One Commerce Plaza, 99 Washington Avenue, Albany, NY 12231.

8. According to its website, Johnson & Johnson is the world's largest and most diverse medical and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing, promotion, training, distribution, and sale of its' pelvic floor repair products, including the product at issue herein. Within J&J there are three business segments, medical devices, pharmaceutical, and consumer. Within the medical devices segment are "Business Units," including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution, and sale of the product at issue in this case. The Chairman for the Ethicon Franchise is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled and managed by J&J and include, but are not limited to Ethicon, Inc.

9. J&J has direct or constructive possession or control of Ethicon's assets and decision-making. Acting through its business units which make up its Medical Devices business segment, including Ethicon, Inc., J&J was involved in the continued research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of medical devices including the TVT device at issue in this case.

10. J&J is a holding company, the purpose of which is: (1) to coordinate the administration, finances, and activities of its subsidiary companies and business units including Ethicon, Inc.; (2) to act as manager; and (3) to direct or coordinate the management of its subsidiary companies and business unites or of the business, property, and estates of any subsidiary company and business units, including Ethicon, Inc.

11. The website on which the pelvic repair mesh products are or were listed, described, and marketed, including the product at issue in this case, has at all times been maintained and operated by J&J. See https://www.jnjmedicaldevices.com/en-US/companies/ethicon (last viewed 3/18/2021).

12. The financial accounts of the Ethicon, Inc. business unit are consolidated within those of J&J. Ethicon's assets and properties are controlled by J&J.

13. J&J is the owner of 100% of the shares of Ethicon, Inc. stock and assets, including the rights to Ethicon, Inc.'s patents and intellectual property. J&J has control over Ethicon Inc.'s activities, operations, and policies.

14. Ethicon, Inc. acts solely as agent for J&J and Ethicon, Inc.'s policies and business operations and decisions have been controlled by J&J. J&J and Ethicon combine their property and labor in a joint venture, enterprise, or undertaking for profit, with rights of mutual control.

15. J&J is liable for any acts and/or omissions by or through Ethicon, Inc. Ethicon, Inc. is organized and controlled, and its business is conducted in such a manner as to make it merely an agent, alter ego, or business conduit of J&J. J&J has not dealt with Ethicon, Inc. at arms-length but instead has dominated and controlled Ethicon, Inc.'s activities, policies, and decisions. For example, J&J has made the decision to restructure the Medical Devices business segment to which the Ethicon business unit belongs as a streamlining and cost-savings measure. J&J's restructuring

of the Medical Devices business segment resulted in a decrease or discontinuation of investment, and research and development with respect to pelvic mesh and other surgical mesh devices and elimination of a sizeable portion of the workforce within the Medical Devices business segment, including many at Ethicon, Inc.

16. J&J has mingled the accounts, records, and property of Ethicon with its own. J&J has held itself out to the public as one entity with business unit/division Ethicon, Inc. J&J has expressly or impliedly assumed Ethicon's liabilities, including liabilities associated with the pelvic mesh product implanted in Plaintiff. J&J insures Ethicon, Inc. and its other business units against product liability claims through a wholly owned, captive insurance company. J&J has paid Ethicon, Inc.'s debts and expenses. Because Ethicon, Inc.'s assets and capital are subject to the ownership and control of J&J, and because the corporate form of Ethicon, Inc. has been disregarded and abused by J&J, Ethicon, Inc. is undercapitalized and the failure to disregard Ethicon, Inc.'s corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Ethicon, Inc. By assuming Ethicon, Inc.'s liabilities, disregarding Ethicon, Inc's corporate form, and by taking affirmative actions to deplete the assets of Ethicon, J&J has promoted a fraud or injustice on Plaintiff.

17. J&J, directly and/or through the actions of its agent and business Ethicon, Inc., has at all pertinent times been responsible for the research, design, development, testing, manufacture, production, marketing, promotion, labeling, distribution, and/or sale of the TVT product at issue in this civil action.

18. Defendants are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture marketing, labeling, distribution, and sale of their TVT product at issue in the instant suit, effectuated directly and

indirectly though their respective agents, servants, employees, and/or owners, all acting within the course and scope of their respective agencies, services, employments, and/or ownership.

19. To the extent that Ethicon claims to maintain any separate corporate identify from J&J, the corporate identify of Ethicon should be pierced so that Ethicon's assets and liabilities are considered the assets and liabilities of J&J, and J&J should be held liable in the same manner as Ethicon, Inc. for any and all of Plaintiff's injuries and damages.

20. Defendants are vicariously liable for the acts and omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

21. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Gynecare TVT. Defendants manufacture, market, advertise, promote, and sell products worldwide.

22. Johnson & Johnson and Ethicon Inc. are collectively referred to herein as "Defendants," "Ethicon Defendants," or "Ethicon."

FACTUAL BACKGROUND

The Pelvic Mesh Products

23. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the GYNECARE TVT. The Pelvic Mesh Product is a product targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the walls of the vagina. The Pelvic Mesh Product is represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene

mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks. It is specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence.

24. Prior the implantation of the Pelvic Mesh Product at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Product under Section 50(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

25. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Product is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

26. The Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

27. Defendants marketed and sold the Pelvic Mesh Product through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

28. Contrary to the representations and marketing of Defendants, the Pelvic Mesh Product has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating revision surgeries, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Betty Dupere. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Product and the immune reaction that results;

b. the design of the Pelvic Mesh Product to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently causes that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Product that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Pelvic Mesh Product into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

29. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of their Pelvic Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of this product, through various means and media, actively and intentionally misleading the public.

30. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Product, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of this device.

31. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Product and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are some of the manufacturers of the products that are the subject of the notification.

32. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear

that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in any manner.

33. Defendants have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Product had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Product and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients

severe injuries and complications.

34. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendants actively and intentionally misled and continue to mislead the public into believing that the Pelvic Mesh Product and the procedures for implantation were and are safe and effective.

35. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Product.

36. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Product; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Product.

37. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter that would have eliminated the risks of Defendants' polypropylene mesh to Plaintiff and to other women like Plaintiff. Safer alternatives may include, for example: the Burch or similar procedure; an autologous fascial or allograft sling, such as Repliform; a sling of lighter weight, larger pore mesh, such as Vypro or Ultrapro; or a sling made of polyethylene or PVDF.

38. The Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

39. Defendants provided incomplete, insufficient, and misleading training and

information to physicians to increase the number of physicians utilizing the Pelvic Mesh Product, and thus increase the sales of this product.

40. The Pelvic Mesh Product implanted into Plaintiff Betty Dupere was in the same or substantially similar condition as it was when it left the possession of Defendants, as well as being in the condition directed by and expected by these Defendants.

41. Plaintiff Betty Dupere and her physician foreseeably used and implanted the Pelvic Mesh Product, and did not misuse or alter this product in an unforeseeable manner.

42. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Product include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

43. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Product) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the device.

44. Defendants knew and had reason to know that the Pelvic Mesh Product could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Product, and that

it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

45. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Product as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

46. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Product.

47. The Pelvic Mesh Product was defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

FACTS SPECIFIC TO PLAINTIFF BETTY DUPERE

48. Upon information and belief, Michael Brodman, M.D. recommended the Pelvic Mesh Product to Plaintiff BETTY DUPERE as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Product.

49. On March 9, 2010, Plaintiff BETTY DUPERE underwent surgery to address her stress urinary incontinence at Mount Sinai Medical Center in New York, New York. During this surgery, she was implanted with an Ethicon Gynecare TVT by Dr. Michael Brodman, M.D.

50. On March 1, 2019, at Wellington Regional Medical Center in Wellington, Florida, Plaintiff BETTY DUPERE underwent surgery to remove the Gynecare TVT sling due to vaginal mesh exposure.

51. As a result of having the Gynecare TVT sling implanted in her, Plaintiff BETTY DUPERE has experienced significant mental and physical pain and suffering, to include

dyspareunia, disabling pelvic pain, infections, recurrence, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

52. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendants' breach of duty occurred until within three years of the filing of this complaint.

53. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within three years of the filing of this complaint. Further, Defendants continue to deny that their products are defective or cause injuries such as those suffered by Plaintiff and Defendants continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendants when Defendants had a duty to disclose and/or by the application of the discovery rule.

54. Neither Plaintiff nor her healthcare providers were warned that the Gynecare TVT device was unreasonably dangerous or of the risks of the devices, outlined herein, even when used exactly as intended by Ethicon Defendants. To the contrary, Defendants promoted and sold the type of transvaginal mesh device implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendants' products.

55. As a direct and proximate result of being surgically implanted with Defendants' unreasonably dangerous transvaginal mesh device, the Gynecare TVT, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. Plaintiff brings this suit for damages related to those injuries.

56. The Gynecare TVT was designed to be permanently implanted into a woman's body yet the product changes after implantation: The TVT contracts over time which, *inter alia,* can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function, and can cause fibrosis of muscles, adhesions between tissues, an inflammation which impairs sexual function, mobility, bowel and bladder function, and causes chronic pelvic pain.

57. The risk of serious injuries was known or should have been known to Ethicon Defendants, but in spite of these risks, Ethicon Defendants continued to market their pelvic mesh devices, including the Gynecare TVT, for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

58. Had Ethicon Defendants properly and adequately disclosed the risks associated with the pelvic mesh product for transvaginal use, including the Gynecare TVT device at issue, Plaintiff would not have agreed to treatment with the device and on information and belief, Plaintiff's implanting physician would have advised her of the risks as part of his informed consent, and/or otherwise altered his prescribing habits, such as recommending a different procedure or device or no surgical treatment.

59. The injuries suffered by Plaintiff were caused by the wrongful acts, and/or omissions, and representations of Ethicon Defendants, as outlined above.

60. As a direct and proximate result of having the Gynecare TVT device implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include any of the following: erosion, urinary tract infections, dyspareunia, recurrence of incontinence, and will likely undergo further medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT I: STRICT LIABILITY – FAILURE TO WARN

61. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if necessary, further alleges as follows:

62. Ethicon Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein.

63. The Pelvic Mesh Product at issue herein was expected to, and did, reach the intended consumers, handlers, and persons receiving the product, including Plaintiff, with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled and marketed by Defendants.

64. The Pelvic Mesh Product at issue herein was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

65. The Pelvic Mesh Product at issue herein implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. The propensities of the Pelvic Mesh Product at issue herein to contract, retract, and/or shrink inside the body;

b. The propensities of the Pelvic Mesh Product at issue herein for degradation, fragmentation, disintegration and/or creep;

c. The inelasticity of the Pelvic Mesh Product at issue preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Product at issue herein;

f. The risk of chronic infections resulting from the Pelvic Mesh Product at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Product at issue herein;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Product at issue herein;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Product at issue herein;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein, including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Product at issue herein;

l. The defects of the Pelvic Mesh Product at issue as described herein;

m. Treatment of stress urinary incontinence with the Gynecare TVT is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Gynecare TVT exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Gynecare TVT makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Product at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Product at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life and intimate personal relationships;

r. Complete removal of the Pelvic Mesh Product at issue herein may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein.

66. Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

67. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Products at issue herein.

68. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages.

69. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

70. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II: STRICT LIABILITY – DEFECTIVE MANUFACTURE AND DESIGN

71. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if necessary, further alleges as follows:

72. The pelvic mesh product at issue herein, the Gynecare TVT device, was designed, marketed, manufactured and distributed by Ethicon Defendants and was defective and not reasonably safe due to their improper, inadequate, and defective design.

73. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein and Plaintiff was an expected user or consumer of the mesh product.

74. The pelvic mesh product at issue herein that was implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh product, like Plaintiff.

75. The pelvic mesh product at issue herein that was implanted in Plaintiff was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the devices.

76. The pelvic mesh product at issue herein that was implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the design defects of the product include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Pelvic Mesh Product at issue herein and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Product at issue herein to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Product at issue herein, including, but not limited to, the propensity of the Pelvic Mesh Product at issue herein to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Product at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Product at issue herein for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Product at issue herein, causing the product to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse and defecation);

g. The propensity of the Pelvic Mesh Product at issue herein for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

k. The hardening of the Pelvic Mesh Product at issue herein in the body;

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

m. The use of polypropylene material in the Pelvic Mesh Product at issue herein and the failure to provide adequate directions for use ("DFU") or instructions for use ("IFU") and training.

77. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

78. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

79. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III: NEGLIGENCE

80. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if same be necessary, further alleges as follows:

81. Defendants had a duty to exercise reasonable case in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Pelvic Mesh Product at issue herein, including the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the products, including Plaintiff herein. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Product at issue herein. Defendants breached the aforementioned duty by, among other things:

a. Failing to design the Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

b. Failing to manufacture the Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Pelvic Mesh Product at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Product at issue herein was implanted, including Plaintiff;

e. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Pelvic Mesh Product at issue herein;

f. Failing to use reasonable care in studying the Pelvic Mesh Product at issue herein to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Pelvic Mesh Product at issue herein.

82. The reasons that Defendants' negligence caused the Pelvic Mesh Product at issue herein to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Pelvic Mesh Product at issue herein and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Product at issue herein to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Product at issue herein, including, but not limited to, the propensity of the Pelvic Mesh Product at issue herein to contract or shrink inside the body, that in turn

cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Product at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Product at issue herein for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Product at issue herein, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Product at issue herein for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the products, which are causally related to infection, as the polypropylene is a foreign material; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

83. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Pelvic Mesh Product's propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Product's propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Product at issue herein;

f. The risk of chronic infections resulting from the Pelvic Mesh Product at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Product at issue herein;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Product at issue herein;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Product at issue herein;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Product at issue herein including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Product at issue herein;

l. The Pelvic Mesh Product's defects described herein;

m. Treatment of stress urinary incontinence with the Pelvic Mesh Product at issue herein is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Pelvic Mesh Product at issue herein exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Pelvic Mesh Product at issue herein makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Product at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Product at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Product at issue herein may not be possible and may not result in complete resolution of the complications, including pain.

84. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

85. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

86. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV: NEGLIGENT MISREPRESENTATION

87. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if necessary, further alleges as follows:

88. The Ethicon Defendants, from the time that the Pelvic Mesh Product were first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to the Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, including, but not limited to, the misrepresentation that the Pelvic Mesh Product was safe, fit, and effective for the treatment of stress urinary incontinence.

89. Defendants owed a duty to Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, to accurately and truthfully represent the risks of the Pelvic Mesh Product. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare

communities, and the public in general about the risks of the Pelvic Mesh Product, which Defendants knew or in the exercise of reasonable diligence should have known.

90. The foregoing representations by Ethicon Defendants were in fact false in that the Pelvic Mesh Product is not, and at all relevant times alleged herein, was not safe, fit, and effective for the treatment of stress urinary incontinence, the use of the Pelvic Mesh Product is hazardous to health, and the Pelvic Mesh Product has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described herein by Plaintiff. The foregoing misrepresentations by Ethicon Defendants were made with the intention of inducing reliance and inducing the purchase and implantation of Pelvic Mesh Product.

91. In reliance on the misrepresentations of Ethicon Defendants, Plaintiff and her prescribing physicians and healthcare providers were induced to purchase and use the Pelvic Mesh Product. If they had known of the true facts and the facts misrepresented by Ethicon Defendants, they would not have used the Pelvic Mesh Product, and their reliance upon Ethicon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

92. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

93. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V: FRAUD

94. Plaintiff repeats and re-alleges the paragraphs above as if specifically set forth herein and additionally or in the alternative, if same be necessary, further alleges as follows:

95. Ethicon Defendants falsely and fraudulently represented to Plaintiff, her physicians, and to members of the general public that the Pelvic Mesh Product was safe, effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer. The representations by Ethicon Defendants were, in fact, false. The true facts include, but are not limited to, that the Pelvic Mesh Product was not safe to be used for treatment of urinary incontinence, and was, in fact, dangerous to the health and body of Plaintiff.

96. When Ethicon Defendants made these representations, they knew that they were false. Ethicon Defendants made said representations with the intent to defraud and deceive Plaintiff and/or her physicians, and with the intent to induce Plaintiff and/or her Physicians to act in the manner herein alleged, that is, to use the aforementioned product for treatment of urinary incontinence.

97. At the time the Ethicon Defendants made the aforesaid representations, Plaintiff and/or her physicians took the actions herein alleged; Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff was and/or her physician were induced to, and did, use the aforesaid Pelvic Mesh Product as herein described. If Plaintiff and/or her physician(s) had known the facts regarding the safety of the Pelvic Mesh Product, neither would not have taken such action. The reliance of Plaintiff and her physicians upon Ethicon Defendants' representations were justified because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

98. As a result of the Ethicon Defendants' fraud and deceit, Plaintiff was caused to sustain the herein described injuries and damages.

99. In doing the acts herein alleged, Ethicon Defendants acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Ethicon Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Ethicon Defendants.

100. As a direct and proximate result of the Ethicon Defendants' fraud, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

101. By reason of the foregoing, Plaintiff has suffered damages for which she now seeks compensation.

102. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI: FRADULENT CONCEALMENT

103. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

104. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Product was defective and unreasonably unsafe for their intended purpose.

105. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, her physicians, and the medical community that their Pelvic Mesh Product was defective, unsafe, unfit for the purposes intended, and not of merchantable quality.

106. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Pelvic Mesh Product because:

a. Defendants were in a superior position to know the true quality, safety, and efficacy of Defendants' Pelvic Mesh Product;

b. Defendants knowingly made false claims about the safety and quality of Defendants' Pelvic Mesh Product in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of Defendants' Pelvic Mesh Product from Plaintiff.

107. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use Defendants' Pelvic Mesh Product.

108. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Pelvic Mesh Product so that Plaintiff would request and purchase Defendants' Pelvic Mesh Product and so that her healthcare providers would dispense, prescribe, and recommend Defendants' Pelvic Mesh Product, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of Defendants' Pelvic Mesh Product.

109. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of Defendants' Pelvic Mesh Product, and are subject to the same liability to Plaintiff for her pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Pelvic Mesh Product's lack of safety and

effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendants are therefore liable for fraudulent concealment under all applicable law, including, inter alia, Restatement of Torts§ 402A.

110. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pelvic pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and economic damages.

111. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII: CONSTRUCTIVE FRAUD

112. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

113. Defendants were in a unique position of knowledge concerning the quality, safety and efficacy of Defendants' Pelvic Mesh Product, with such knowledge not possessed by Plaintiff or her physicians, and Defendants thereby hold a position of superiority over Plaintiff.

114. Despite their unique knowledge regarding the defective nature of Defendants' Pelvic Mesh Product, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of Defendants' Pelvic Mesh Product as compared to other products and forms of treatment.

115. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that Defendants' Pelvic Mesh Product had a higher risk of adverse effects in addition to and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Pelvic Mesh Product.

116. Upon information and belief, Defendants' misrepresentations were designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase Defendants' Pelvic Mesh Product. Plaintiff and the medical community have relied upon Defendants' representations.

117. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendants' representations.

118. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pelvic pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and economic damages.

119. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII: VIOLATION OF NEW YORK CONSUMER PROTECTION ACT

120. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

121. Plaintiff purchased and used Defendants' Pelvic Mesh Product primarily ·for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

122. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendants' Pelvic Mesh Product and would not have incurred related medical costs and injury.

123. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

124. Defendants engaged in unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

125. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of Defendants' Pelvic Mesh Product.

126. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Defendants' Pelvic Mesh Product.

127. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product, would not have consented to their implantation, and would not have incurred related medical costs.

128. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

129. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

130. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Article 22-A - (349 - 350-F-1).

131. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants were the suppliers, manufacturers, advertisers, and sellers subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

132. Defendants violated the statute that was enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that Defendants' Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

133. The acts and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

134. Defendants had actual knowledge of the defective and dangerous condition of Defendants' Pelvic Mesh Product and failed to take any action to cure such defective and dangerous conditions.

135. Plaintiff's healthcare providers and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

136. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

137. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

138. As a direct and proximate result of Defendants' violations of the state's consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

139. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX: GROSS NEGLIGENCE

140. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

141. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards, (1) was specifically intended to cause substantial injury to Plaintiff; (2) when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, that Defendants were actually, subjectively aware, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or (3) otherwise included a material representation that was false, despite Defendants' knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation was acted on by Plaintiff.

142. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

143. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

144. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct while deterring other manufacturers from engaging in such misconduct in the future.

145. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

PUNITIVE DAMAGES

146. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, gross negligence, wanton and reckless conduct, and their complete and total reckless disregard for the public safety and welfare.

147. Defendants had knowledge of or should have had knowledge of, and/or were in possession of evidence demonstrating that the Pelvic Mesh Product at issue was defective and unreasonably dangerous and/or was an inappropriate choice for treatment of Plaintiff's SUI. Despite this knowledge, Defendants failed to, among other purposeful acts, inform or warn of the dangers, establish and maintain an adequate quality and post-market or post-implant surveillance system, and/or recall the Pelvic Mesh Product.

148. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical and mental injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

DISCOVERY RULE AND TOLLING

149. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

150. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

151. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence

should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, .and the tortious nature of the wrongdoing that caused the injury.

152. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Product was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

153. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and her healthcare providers of the true risks associated with the Product.

154. As a result of Defendants' fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendants.

CONCLUSION AND PRAYER

WHEREFORE, Plaintiff demands judgment jointly and severally against the Defendants and for all causes of action alleged above and requests damages.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Date: March 25, 2021.

Respectfully submitted,

/s/ Laura J. Baughman
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